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(71) Applicant (*for all designated States except US*): THE MOWER FAMILY CHF TREATMENT IRREVOCABLE TRUST [US/US]; Suite 501, Two East Fayatte Street, Baltimore, MD 21202 (US).

(72) Inventor; and
(75) Inventor/Applicant (*for US only*): MOWER, M., D., Morton, M. [US/US]; 3908 North Charles Street #1001, Baltimore, MD 21218 (US).

(74) Agents: ROBERTS, Jon, L. et al.; Roberts Abokhair & Mardula, LLC, Suite 1000, 11800 Sunrise Valley Drive, Reston, VA 20191-5302 (US).

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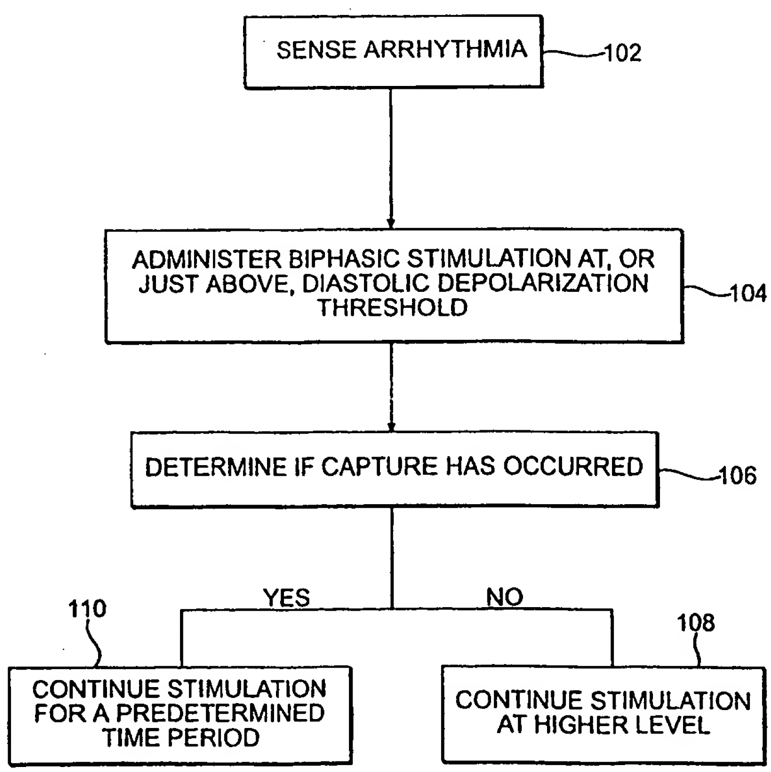
(54) Title: ANTITACHYCARDIAL PACING

(57) Abstract

Protocols for antitachycardial pacing including biphasic stimulation administered at, or just above, the diastolic depolarization the shold potential; biphasic or conventional stimulation initiated at, or just above, the diastolic depolarization threshold potential, reduced, upon capture, to below threshold; and biphasic or conventional stimulation administered at a level set just below the diastolic depolarization threshold potential. These protocols result in reliable cardiac capture with a lower stimulation level, thereby causing less damage to the heart, extending battery life, causing less pain to the patient and having greater therapeutic effectiveness. In those protocols using biphasic cardiac pacing, a first and second stimulation phase is administered. The first stimulation phase has a predefined polarity, amplitude and duration. The second stimulation phase also has a predefined polarity, amplitude and duration. The two phases are applied sequentially. Contrary to current trought, anodal stimulation is first applied and followed by cathodal stimulation. In this fashion, pulse conduction through the cardiac muscle is improved together with the increase in contractility.



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Title: ANTITACHYCARDIAL PACING

Inventor: Morton M. Mower, M.D.

Field of the Invention

The present invention relates generally to implantable cardioverter/defibrillator with antitachycardial pacing capabilities and/or a method of such pacing.

Background of the Invention

The typical implantable cardioverter/defibrillator (ICD) delivers an initial electrical countershock within ten to twenty seconds of arrhythmia onset, thereby saving countless lives. Improved devices have antitachycardia pacing capabilities in addition to cardioverting/defibrillating functions. These ICDs are capable of different initial responses to one or more tachycardia as well as a programmable sequence of responses to a particular arrhythmia.

The output energy level is generally set by a physician in accordance with a patient's capture threshold, determined at the time of heart implantation. This threshold represents the minimum pacing energy required to reliably stimulate a patient's heart. However, due to trauma associated with the stimulation, scar tissue grows at the interface between the implanted cardiac pacer leads and the myocardium. This scar tissue boosts the patient's capture threshold. To insure reliable cardiac capture, the output energy level is thus generally set at a level which is a minimum of two times greater than the initially measured capture threshold. A drawback to such an approach is that the higher stimulation level causes more trauma to the cardiac tissue than would a lower level of stimulation, and hence promotes the formation of scar tissue, thereby boosting the capture threshold.

The higher stimulation level also shortens battery life. This is not desirable, as a

shorter battery life necessitates more frequent surgery to implant fresh batteries.

Another drawback is the potential for patient discomfort associated with this higher stimulation level. This is because the higher stimulation level can stimulate the phrenic or diaphragmatic plexus or cause intercostal muscle pacing.

Lastly, the higher stimulation is less effective, due to entry block.

A need therefore exists for an ICD that can achieve reliable cardiac capture with a lower stimulation level, thereby causing less damage to the heart, extending battery life, causing less pain to the patient and having greater therapeutic effectiveness than current ICDs. A need also exists for an ICD that can better entrain the heart and can entrain portions of the heart from a greater distance.

Summary of the Invention

It therefore is an object of the present invention to provide an ICD with antitachycardial pacing capabilities, wherein the stimulation is administered with a voltage either at, just above, or just below the diastolic depolarization threshold potential.

It is another object of the present invention to sense whether cardiac capture has occurred, and if not, to administer additional stimulation.

It is another object of the present invention to provide the additional stimulation at a slightly higher voltage level than that level of stimulation which resulted in no capture.

It is another object of the present invention to repeat the stimulation - sensing cycle until cardiac capture has occurred.

It is another object of the present invention to provide stimulation using a biphasic waveform.

The present invention accomplishes the above objectives by providing an implantable cardioverter-defibrillator with a unique constellation of features and capabilities. Protocols

disclosed include:

1/ biphasic stimulation administered at, or just above, the diastolic depolarization threshold potential;

2/ biphasic or conventional stimulation initiated at, or just above, the diastolic depolarization threshold potential, reduced, upon capture, to below threshold; and

3/ biphasic or conventional stimulation administered at a level set just below the diastolic depolarization threshold potential.

As mentioned, the antitachycardial pacing protocols of the present invention can be used in conjunction with biphasic pacing. The method and apparatus relating to biphasic pacing comprises a first and second stimulation phase, with each stimulation phase having a polarity, amplitude, shape, and duration. In a preferred embodiment, the first and second phases have differing polarities. In one alternative embodiment, the two phases are of differing amplitude. In a second alternative embodiment, the two phases are of differing duration. In a third alternative embodiment, the first phase is in a chopped wave form. In a fourth alternative embodiment, the amplitude of the first phase is ramped. In a fifth alternative embodiment the first phase is administered over 200 milliseconds after completion of a cardiac beating/pumping cycle. In a preferred alternative embodiment, the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration, and the second phase of stimulation is a cathodal pulse of short duration and high amplitude. It is noted that the aforementioned alternative embodiments can be combined in differing fashions. It is also noted that these alternative embodiments are intended to be presented by way of example only, and are not limiting.

Enhanced myocardial function is obtained through the biphasic pacing of the present invention. The combination of cathodal with anodal pulses of either a stimulating or

conditioning nature, preserves the improved conduction and contractility of anodal pacing while eliminating the drawback of increased stimulation threshold. The result is a depolarization wave of increased propagation speed. This increased propagation speed results in superior cardiac contraction leading to an improvement in blood flow and in increased access to reentrant circuits. Improved stimulation at a lower voltage level also results in reduction in scar tissue buildup thereby reducing the tendency of the capture threshold to rise; reduction in power consumption leading to increased life for pacemaker batteries; and decreased pain to the patient.

Brief Description of the Drawings

Figs. 1A-1C illustrate examples of methodologies for treating arrhythmias.

Fig. 2 illustrates a schematic representation of leading anodal biphasic stimulation.

Fig. 3 illustrates a schematic representation of leading cathodal biphasic stimulation.

Fig. 4 illustrates a schematic representation of leading anodal stimulation of low level and long duration, followed by conventional cathodal stimulation.

Fig. 5 illustrates a schematic representation of leading anodal stimulation of ramped low level and long duration, followed by conventional cathodal stimulation.

Fig. 6 illustrates a schematic representation of leading anodal stimulation of low level and short duration, administered in series followed by conventional cathodal stimulation.

Fig. 7 illustrates an implantable cardioverter/defibrillator useable for implementing embodiments of the present invention.

Description of the Preferred Embodiments

The present invention relates to the use of antitachycardial pacing to break up arrhythmia in the atrium. **Figs. 1A through 1C** illustrate examples of methodologies for treating arrhythmias.

Fig. 1A illustrates a first methodology. Here, a sensor senses the onset of arrhythmia **102**. In a preferred embodiment, this sensor comprises an antitachycardial pacing algorithm. Biphasic stimulation is then administered **104**. In varying embodiments, this stimulation is either at, or just above the diastolic depolarization threshold. The ICD determines whether capture has occurred **106**. If capture has not occurred, then stimulation continues at a slightly higher level **108**. This stimulation - capture check - boost stimulation cycle continues until capture occurs. If capture has occurred, then stimulation is continued for a predetermined period of time **110**. In a preferred embodiment, stimulation is administered as long as the arrhythmia persists.

In a preferred embodiment, stimulation pulses are administered at 80 to 100 percent of the intrinsic rate with an approximately one to two second pause between each set of stimulation pulses. Then either the number of pulses increases, or the timing between pulses is adjusted. For example, in a preferred embodiment, the first pulse sequence can be at 80 percent of the intrinsic heart rate, the second pulse sequence at 82 percent, the third pulse sequence at 84 percent, and so on. In a preferred embodiment a plurality of feedback loops provide data such that the voltage can be adjusted to constantly skirt the capture threshold. Stimulation is continued until the rhythm reverts.

Fig. 1B illustrates a second methodology. Here, a sensor senses the onset of arrhythmia **112**. In varying embodiments of the second method, either biphasic or conventional stimulation is then administered **114**. This stimulation level is set at or just above the diastolic depolarization threshold potential. The ICD determines whether capture has occurred **116**. If capture has not occurred, then stimulation continues at a slightly higher level **118**. This stimulation - capture check - boost stimulation cycle continues until capture occurs. If capture has occurred, then stimulation is gradually and continuously reduced to

below threshold, and continued **120**. Then, if capture is lost, the stimulation is raised to a slightly higher level and is again gradually and continuously reduced. This entire sequence is repeated, such that the stimulation level hovers as close as possible to the lowest stimulation level which provides capture. Stimulation continues until the rhythm reverts, for example, when the antitachycardial pacing algorithm determines that pacing is no longer necessary.

Fig. 1C illustrates a third methodology. Here, a sensor senses the onset of arrhythmia **122**. In varying embodiments of the third method, either biphasic or conventional stimulation is then administered **124**. This stimulation level is set just below the diastolic depolarization threshold potential. The ICD determines whether capture has occurred **126**. If capture has not occurred, then stimulation continues at a slightly higher level **128**. This stimulation - capture check - boost stimulation cycle continues until capture occurs. If capture has occurred, then stimulation is continued at below threshold level **130**. If capture is lost then the stimulation is raised to a slightly higher level and is gradually and continuously reduced. This entire sequence is repeated, such that the stimulation level hovers as close as possible to the lowest stimulation level which provides capture. Stimulation continues until the rhythm reverts, for example, when the antitachycardial pacing algorithm determines that pacing is no longer necessary.

<u>Sensing</u>

Sensing can be direct or indirect. For example, direct sensing can be based on data from sensing electrodes. The ICD of the present invention includes sensing circuits/electronics to sense an arrhythmia through one or more sensing and/or stimulating electrodes. The sensing electronics sense the cardiac activity as depicted by electrical signals. For example, as is known in the art, R-waves occur upon the depolarization of ventricular tissue and P-waves occur upon the depolarization of atrial tissue. By monitoring these

electrical signals the control/timing circuit of the ICD can determine the rate and regularity of the patient's heart beat, and thereby determine whether the heart is undergoing arrhythmia. This determination can be made by determining the rate of the sensed R-waves and/or P-waves and comparing this determined rate against various reference rates.

Direct sensing can be based upon varying criteria; such as, but not limited to, primary rate, sudden onset, and stability. The sole criteria of a primary rate sensor is the heart rate. When applying the primary rate criteria, if the heart rate should exceed a predefined level, then treatment is begun. Sensing electronics set to sudden onset criteria ignore those changes which occur slowly, and initiate treatment when there is a sudden change such as immediate paroxysmal arrhythmia. This type of criteria would thus discriminate against sinus tachycardia. Stability of rate can also be an important criteria. For example, treatment with a ventricular device would not be warranted for a fast rate that varies, here treatment with an atrial device would be indicated.

In alternative embodiments, sensing can be indirect. Indirect sensing can be based on any of various functional parameters such as arterial blood pressure, rate of the electrocardiogram deflections or the probability density function (pdf) of the electrocardiogram. For example, whether or not to administer treatment can also be affected by pdf monitoring of the time the signal spends around the baseline.

Sensing can also be augmented by stimulating the atria and observing and measuring the consequent effects on atrial and ventricular function.

Thus, in a preferred embodiment, sensing electronics are based upon multiple criteria. In addition, the present invention envisions devices working in more than one chamber such that appropriate treatment can be administered to either the atrium or the ventricle in response to sensing electronics based upon a variety of criteria, including those described above as well

as other criteria known to those skilled in the art.

Stimulation

Electrical stimulation is delivered via lead(s) or electrode(s). These leads can be epicardial (external surface of the heart) or endocardial (internal surface of the heart) or any combination of epicardial and endocardial. Leads are well known to those skilled in the art; see, for example, United States Patent Nos. 4662377 to Heilman et al., 4481953 to Gold et al., and 4010758 to Rockland et al., each of which is herein incorporated by reference in its entirety.

Lead systems can be unipolar or bipolar. A unipolar lead has one electrode on the lead itself, the cathode. Current flows from the cathode, stimulates the heart, and returns to the anode on the casing of the pulse generator to complete the circuit. A bipolar lead has two poles on the lead a short distance from each other at the distal end, and both electrodes lie within the heart.

With the reference to **Fig. 7**, an exemplary system by which the present invention may be embodied is illustrated. An automatic implantable cardioverter/defibrillator **2** is implanted within the body of the patient and has a pair of output terminals, an anode **4** and a cathode **6**. The ICD **2** is coupled to a flexible catheter electrode arrangement **8** having a distal electrode **10** and a proximal electrode **12**, each associated with the patient's heart. Other electrode configurations may be employed, such as ring-type electrodes. As for external electrodes, an anodal electrode **24** may be employed. The automatic ICD **2** includes sensing and detecting circuitry, as well as pulse generating circuitry, the output of the latter being coupled to the implantable electrodes **10**, **12**. The ICD **2** senses an arrhythmic condition of the heart and, in response thereto, issues or emits cardioverting or defibrillating pulses to the heart, through the implantable electrodes **10**, **12**.

The catheter electrode **8** is inserted intravenously to a position such that the distal electrode **10** is positioned in the right ventricular apex **14** of the heart and the proximal electrode **12** is positioned in the superior vena cava region **16** of the heart. It should be appreciated that, as the term is used herein, the superior vena cava **16** may also include portions of the right atrium **18**.

Conventional stimulation is well known to those skilled in the art and comprises monophasic waveforms (cathodal or anodal) as well as multiphasic waveforms wherein the nonstimulating pulses are of a minimal magnitude and are used, for example, to dissipate a residual charge on an electrode.

Figs. 2 through 6 depict a range of biphasic stimulation protocols. These protocols have been disclosed in United States Patent Application No. 08/699,552 to Mower, which is herein incorporated by reference in its entirety.

Fig. 2 depicts biphasic electrical stimulation wherein a first stimulation phase comprising anodal stimulus **102** is administered having amplitude **104** and duration **106**. This first stimulation phase is immediately followed by a second stimulation phase comprising cathodal stimulation **108** of equal intensity and duration.

Fig. 3 depicts biphasic electrical stimulation wherein a first stimulation phase comprising cathodal stimulation **202** having amplitude **204** and duration **206** is administered. This first stimulation phase is immediately followed by a second stimulation phase comprising anodal stimulation **208** of equal intensity and duration.

Fig. 4 depicts a preferred embodiment of biphasic stimulation wherein a first stimulation phase, comprising low level, long duration anodal stimulation **302** having amplitude **304** and duration **306**, is administered. This first stimulation phase is immediately

followed by a second stimulation phase comprising cathodal stimulation **308** of conventional intensity and duration. In differing alternative embodiments, anodal stimulation **302** is: 1) at maximum subthreshold amplitude; 2) less than three volts; 3) of a duration of approximately two to eight milliseconds; and/or 4) administered over 200 milliseconds post heart beat. Maximum subthreshold amplitude is understood to mean the maximum stimulation amplitude that can be administered without eliciting a contraction. In a preferred embodiment, anodal stimulation is approximately two volts for approximately three milliseconds duration. In differing alternative embodiments, cathodal stimulation **308** is: 1) of a short duration; 2) approximately 0.3 to 1.5 milliseconds; 3) of a high amplitude; 4) in the approximate range of three to twenty volts; and/or 5) of a duration less than 0.3 millisecond and at a voltage greater than twenty volts. In a preferred embodiment, cathodal stimulation is approximately six volts administered for approximately 0.4 millisecond. In the manner disclosed by these embodiments, as well as those alterations and modifications which can become obvious upon the reading of this specification, a maximum membrane potential without activation is achieved in the first phase of stimulation.

Fig. 5 depicts an alternative preferred embodiment of biphasic stimulation wherein a first stimulation phase, comprising anodal stimulation **402**, is administered over period **404** with rising intensity level **406**. The ramp of rising intensity level **406** can be linear or non-linear, and the slope can vary. This anodal stimulation is immediately followed by a second stimulation phase comprising cathodal stimulation **408** of conventional intensity and duration. In alternative embodiments, anodal stimulation **402**: (1) rises to a maximum subthreshold amplitude less than three volts; (2) is of a duration of approximately two to eight milliseconds; and/or (3) is administered over 200 milliseconds post heart beat. In yet other alternative embodiments, cathodal stimulation **408** is: (1) of a short duration; (2)

approximately 0.3 to 1.5 milliseconds; (3) of a high amplitude; (4) in the approximate range of three to twenty volts; and/or (5) of a duration less than 0.3 milliseconds and at a voltage greater than twenty volts. In the manner disclosed by these embodiments, as well as those alterations and modifications which can become obvious upon the reading of this specification, a maximum membrane potential without activation is achieved in the first phase of stimulation.

Fig. 6 depicts biphasic electrical stimulation wherein a first stimulation phase, comprising series **502** of anodal pulses, is administered at amplitude **504**. In one embodiment, rest period **506** is of equal duration to stimulation period **508**, and is administered at baseline amplitude. In an alternative embodiment, rest period **506** is of a differing duration than stimulation period **508**, and is administered at baseline amplitude. Rest period **506** occurs after each stimulation period **508**, with the exception that a second stimulation phase, comprising cathodal stimulation **510** of conventional intensity and duration, immediately follows the completion of series **502**. In alternative embodiments: (1) the total charge transferred through series **502** of anodal stimulation is at the maximum subthreshold level; and/or (2) the first stimulation pulse of series **502** is administered over 200 milliseconds post heart beat. In yet other alternative embodiments, cathodal stimulation **510** is: (1) of a short duration; (2) approximately 0.3 to 1.5 milliseconds; (3) of a high amplitude; (4) in the approximate range of three to twenty volts, and/or (5) of a duration less than 0.3 milliseconds and at a voltage greater than twenty volts.

<u>Determining Cardiac Capture</u>

Capture can be determined by multiple means. First, capture or the loss thereof, can be determined by monitoring cardiac rhythm. Loss of capture can result in a change in timing of the heart beat.

Second, capture can be monitored through the development of a template. The template can be based on parameters such as electrocardiogram data, mechanical motion and/or probability density function data. Where the template is established pre-stimulation, a change in the baseline signifies capture. Where the template is established after capture has occurred, a change in the template characteristics signifies loss of capture. The templates can be established and/or updated at any time.

Once capture occurs the stimulation protocol of the entrained sites is adjusted as illustrated by Figs. 1A through 1C.

Having thus described the basic concept of the invention, it will be readily apparent to those skilled in the art that the foregoing detailed disclosure is intended to be presented by way of example only, and is not limiting. Various alterations, improvements and modifications will occur and are intended to those skilled in the art, but are not expressly stated herein. These modifications, alterations and improvements are intended to be suggested hereby, and within the scope of the invention. Further, the pacing pulses described in this specification are well within the capabilities of existing pacemaker electronics with appropriate programming. Accordingly, the invention is limited only by the following claims and equivalents thereto.

What is claimed is:

1. An implantable cardioverter-defibrillator (ICD), the ICD comprising:

sensing means for sensing the onset of arrhythmia;

output means for delivering, in response to the sensing means, electrical stimulation of a predetermined polarity, amplitude, shape and duration to cause application of biphasic stimulation at a first intensity level selected from the group consisting of: at the diastolic depolarization threshold, below the diastolic depolarization threshold, and above the diastolic depolarization threshold; and

means for determining whether capture has occurred;

wherein biphasic stimulation comprises:

a first stimulation phase with a first phase polarity, a first phase amplitude, a first phase shape and a first phase duration; and

a second stimulation phase with a second phase polarity, a second phase amplitude, a second phase shape and a second phase duration.

2. The ICD as in claim 1, wherein in the event that the means for determining determines that capture has not occurred, the output means increases the stimulation intensity level by predefined increments until capture occurs.

3. The ICD as in claim 1, wherein in the event that the means for determining determines that capture has occurred, the output means continues biphasic stimulation for a predetermined period of time.

4. The ICD as in claim 1, wherein in the event that the means for determining determines that capture has occurred, the output means halts biphasic stimulation.

5. The ICD as in claim 1, wherein the first phase polarity is positive.

6. The ICD as in claim 1, wherein the first phase amplitude is less than the second

phase amplitude.

7. The ICD as in claim **1**, wherein the first phase amplitude is ramped from a baseline value to a second value.

8. The ICD as in claim **7**, wherein the second value is equal to the second phase amplitude.

9. The ICD as in claim **7**, wherein the second value is at a maximum subthreshold amplitude.

10. The ICD as in claim **9**, wherein the maximum subthreshold amplitude is about 0.5 to 3.5 volts.

11. The ICD as in claim **7**, wherein the first phase duration is at least as long as the second phase duration.

12. The ICD as in claim **7**, wherein the first phase duration is about one to nine milliseconds.

13. The ICD as in claim **7**, wherein the second phase duration is about 0.2 to 0.9 milliseconds.

14. The ICD as in claim **7**, wherein the second phase amplitude is about two volts to twenty volts.

15. The ICD as in claim **7**, wherein the second phase duration is less than 0.3 milliseconds and the second phase amplitude is greater than 20 volts.

16. The ICD as in claim **1**, wherein the first stimulation phase further comprises a series of stimulating pulses of a predetermined amplitude, polarity and duration.

17. The ICD as in claim **16**, wherein the first stimulation phase further comprises a series of rest periods.

18. The ICD as in claim **17**, wherein applying the first stimulation phase further

comprises applying a rest period of a baseline amplitude after at least one stimulating pulse.

19. The ICD as in claim **18**, wherein the rest period is of equal duration to the duration of the stimulating pulse.

20. The ICD as in claim **1**, wherein the first phase amplitude is at a maximum subthreshold amplitude.

21. The ICD as in claim **20**, wherein the maximum subthreshold amplitude is about 0.5 to 3.5 volts.

22. The ICD as in claim **1**, wherein the first phase duration is at least as long as the second phase duration.

23. The ICD as in claim **1**, wherein the first phase duration is about one to nine milliseconds.

24. The ICD as in claim **1**, wherein the second phase duration is about 0.2 to 0.9 milliseconds.

25. The ICD as in claim **1**, wherein the second phase amplitude is about two volts to twenty volts.

26. The ICD as in claim **1**, wherein the second phase duration is less than 0.3 milliseconds and the second phase amplitude is greater than 20 volts.

27. The ICD as in claim **1**, wherein the first stimulation phase is initiated greater than 200 milliseconds after completion of a cardiac beating cycle.

28. A method of operating an implantable cardioverter-defibrillator (ICD), the ICD having output means for delivering electrical stimulation of a predetermined polarity, amplitude, shape and duration, the method comprising:

sensing the onset of arrhythmia;

applying stimulation selected from the group consisting of biphasic stimulation and

conventional stimulation at a first intensity level selected from the group consisting of at the diastolic depolarization threshold, below the diastolic depolarization threshold or above the diastolic depolarization threshold;

determining whether capture has occurred;

increasing the stimulation intensity level by predefined increments until capture does occurs; and upon capture,

continuing stimulation selected from the group consisting of biphasic stimulation and conventional stimulation at a second intensity level below the diastolic depolarization threshold.

29. A method of operating an implantable cardioverter-defibrillator (ICD), the ICD having output means for delivering electrical stimulation of a predetermined polarity, amplitude, shape and duration, the method comprising:

defining a first stimulation phase with a positive polarity, a first phase amplitude, a first phase shape and a first phase duration, wherein said first phase amplitude is about 0.5 to 3.5 volts, wherein said first phase duration is about one to nine milliseconds and wherein said first stimulation phase is initiated greater than 200 milliseconds after completion of a cardiac beating cycle;

defining a second phase with a negative polarity, a second phase amplitude, a second phase shape and a second phase duration, wherein said second phase amplitude is about four volts to twenty volts and wherein said second phase duration is about 0.2 to 0.9 milliseconds; and

sensing the onset of arrhythmia;

applying the first stimulation phase and the second stimulation phase in sequence to

the cardiac tissue;

determining whether capture has occurred; and

increasing the stimulation intensity level by predefined increments until capture occurs.

30. A method of operating an implantable cardioverter-defibrillator (ICD), the ICD having output means for delivering electrical stimulation of a predetermined polarity, amplitude, shape and duration, the method comprising:

sensing the onset of arrhythmia;

applying biphasic stimulation at a first intensity level selected from the group consisting of at the diastolic depolarization threshold, below the diastolic depolarization threshold or above the diastolic depolarization threshold wherein biphasic stimulation comprises:

a first stimulation phase with a first phase polarity, a first phase amplitude, a first phase shape and a first phase duration; and

a second stimulation phase with a second phase polarity, a second phase amplitude, a second phase shape and a second phase duration; and

determining whether capture has occurred.

31. An implantable cardiac stimulator device comprising:

plural electrodes;

sensing circuitry connected to the plural electrodes and adapted to sense the onset of arrhythmia;

detecting circuitry connected to the sensing circuitry and adapted to detect whether capture has occurred; and

pulse generating circuitry connected to the plural electrodes and adapted to generate,

in response to the sensing circuitry, electrical pulses of a predetermined polarity, amplitude, shape and duration to cause application of biphasic stimulation at a first intensity level selected from the group consisting of: at the diastolic depolarization threshold, below the diastolic depolarization threshold, and above the diastolic depolarization threshold; and

wherein biphasic stimulation comprises:

a first stimulation phase with a first phase polarity, a first phase amplitude, a first phase shape and a first phase duration; and

a second stimulation phase with a second phase polarity, a second phase amplitude, a second phase shape and a second phase duration.

32. The implantable cardiac stimulator device as in claim **31**, wherein, in the event that the detecting circuitry determines that capture has not occurred, the pulse generating circuitry increases the stimulation intensity level by predefined increments until capture occurs.

33. The implantable cardiac stimulator device as in claim **31**, wherein, in the event that the detecting circuitry determines that capture has occurred, the pulse generating circuitry continues biphasic stimulation for a predetermined period of time.

34. The implantable cardiac stimulator device as in claim **31**, wherein, in the event that the detecting circuitry determines that capture has occurred, the pulse generating circuitry halts biphasic stimulation.

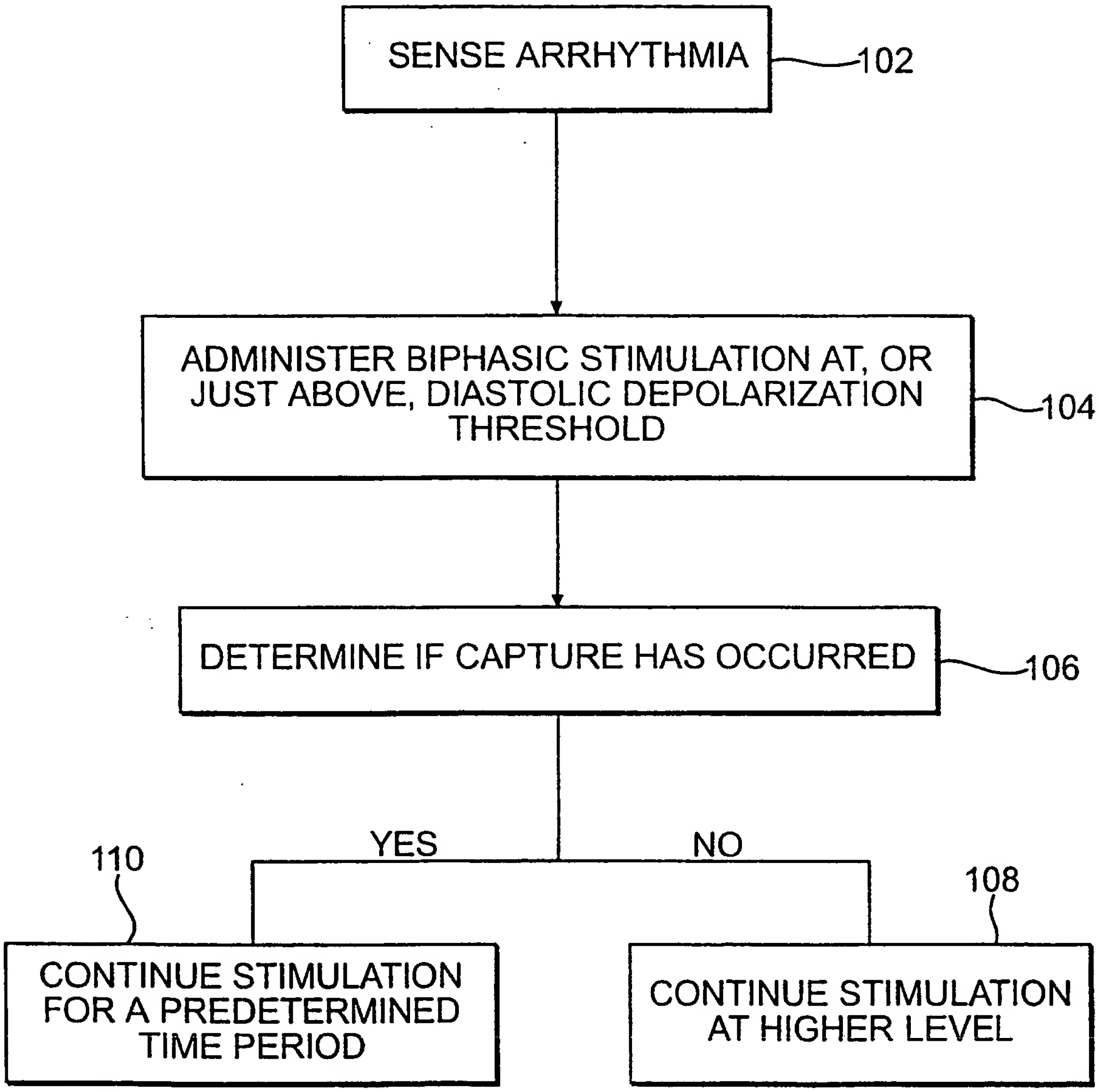
SENSE ARRHYTHMIA
102
ADMINISTER BIPHASIC STIMULATION AT, OR JUST ABOVE, DIASTOLIC DEPOLARIZATION THRESHOLD
104
DETERMINE IF CAPTURE HAS OCCURRED
106
YES
NO
110
108
CONTINUE STIMULATION FOR A PREDETERMINED TIME PERIOD
CONTINUE STIMULATION AT HIGHER LEVEL

FIG. 1A

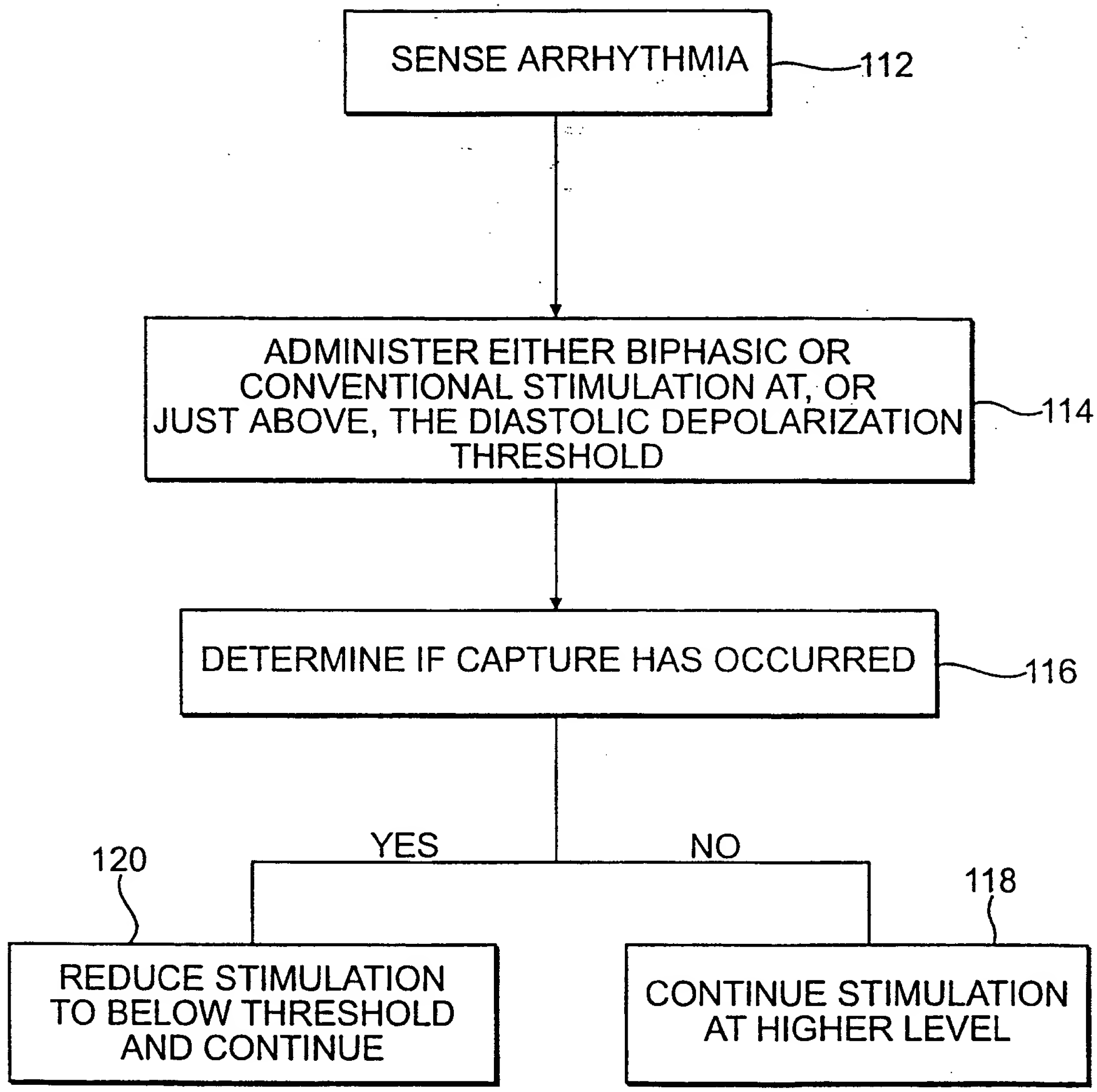
SENSE ARRHYTHMIA
112
ADMINISTER EITHER BIPHASIC OR CONVENTIONAL STIMULATION AT, OR JUST ABOVE, THE DIASTOLIC DEPOLARIZATION THRESHOLD
114
DETERMINE IF CAPTURE HAS OCCURRED
116
YES
NO
120
118
REDUCE STIMULATION TO BELOW THRESHOLD AND CONTINUE
CONTINUE STIMULATION AT HIGHER LEVEL

FIG. 1B

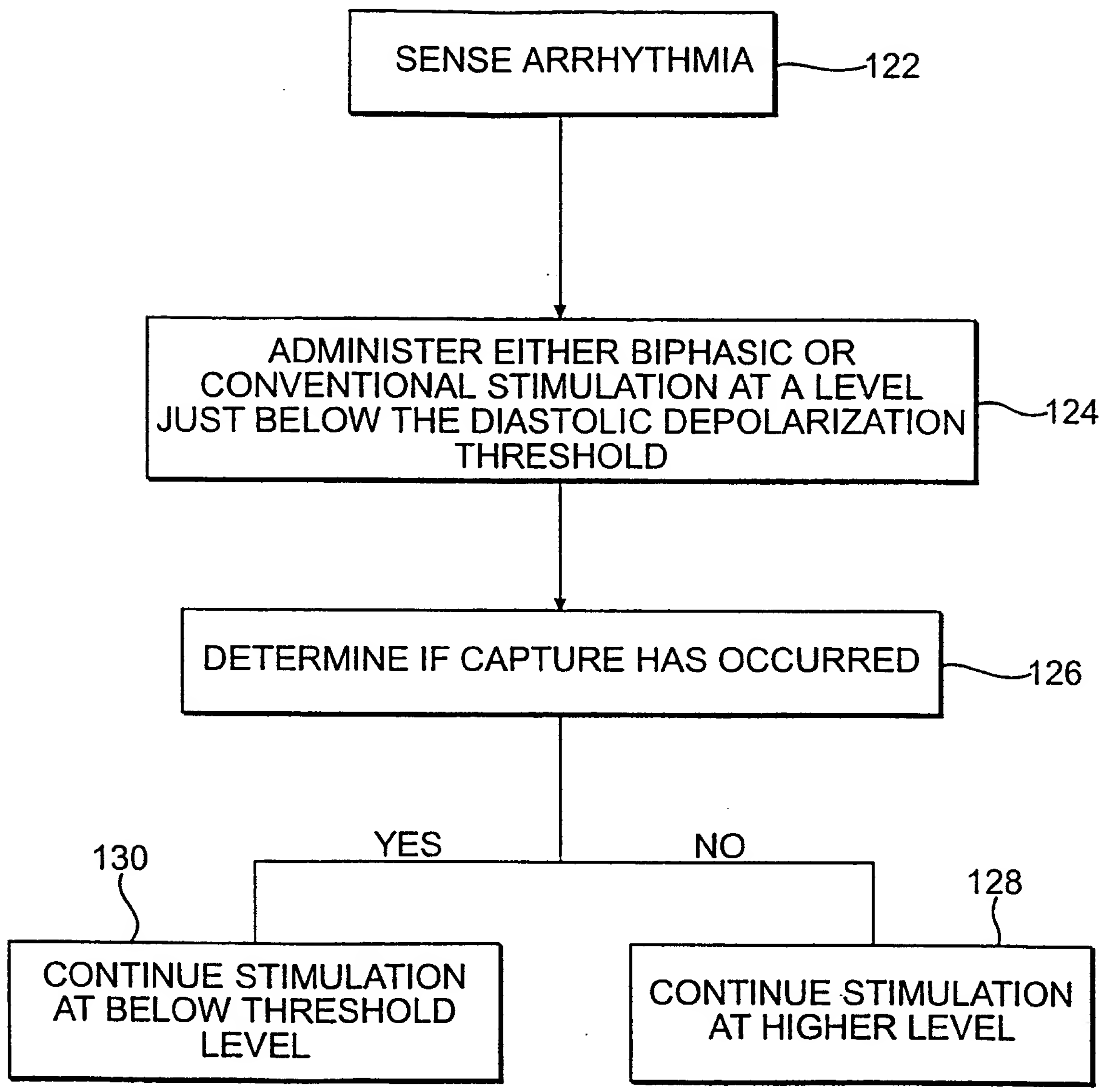
SENSE ARRHYTHMIA
122
ADMINISTER EITHER BIPHASIC OR CONVENTIONAL STIMULATION AT A LEVEL JUST BELOW THE DIASTOLIC DEPOLARIZATION THRESHOLD
124
DETERMINE IF CAPTURE HAS OCCURRED
126
YES
NO
130
128
CONTINUE STIMULATION AT BELOW THRESHOLD LEVEL
CONTINUE STIMULATION AT HIGHER LEVEL

FIG. 1C

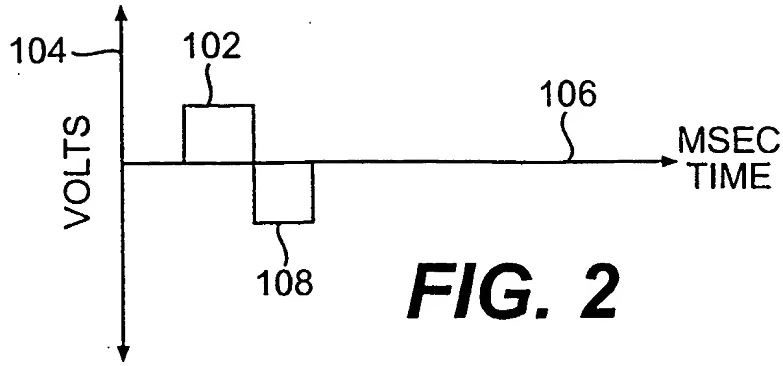

FIG. 2

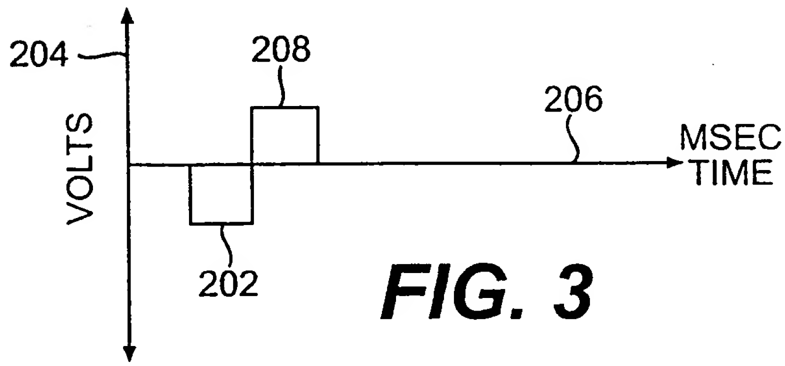

FIG. 3

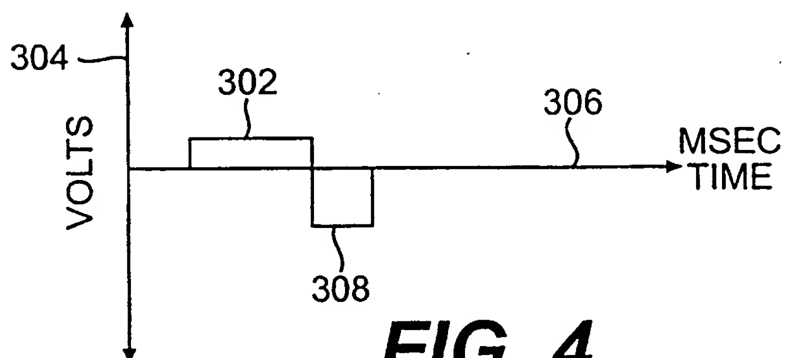

FIG. 4

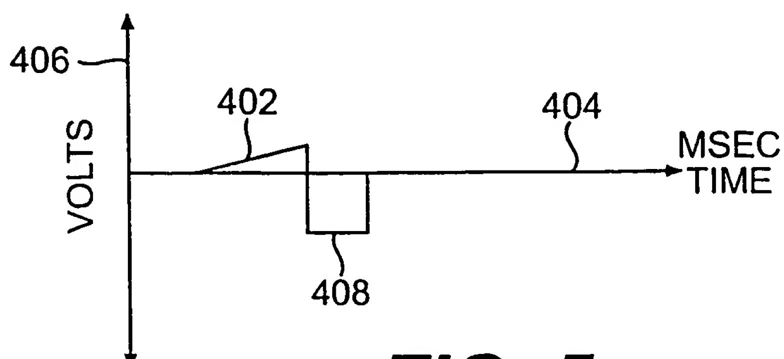

FIG. 5

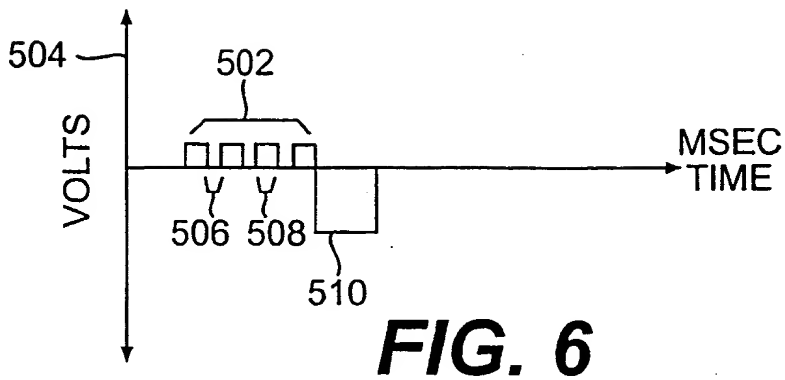
504
502
VOLTS
MSEC
TIME
506
508
510

FIG. 6

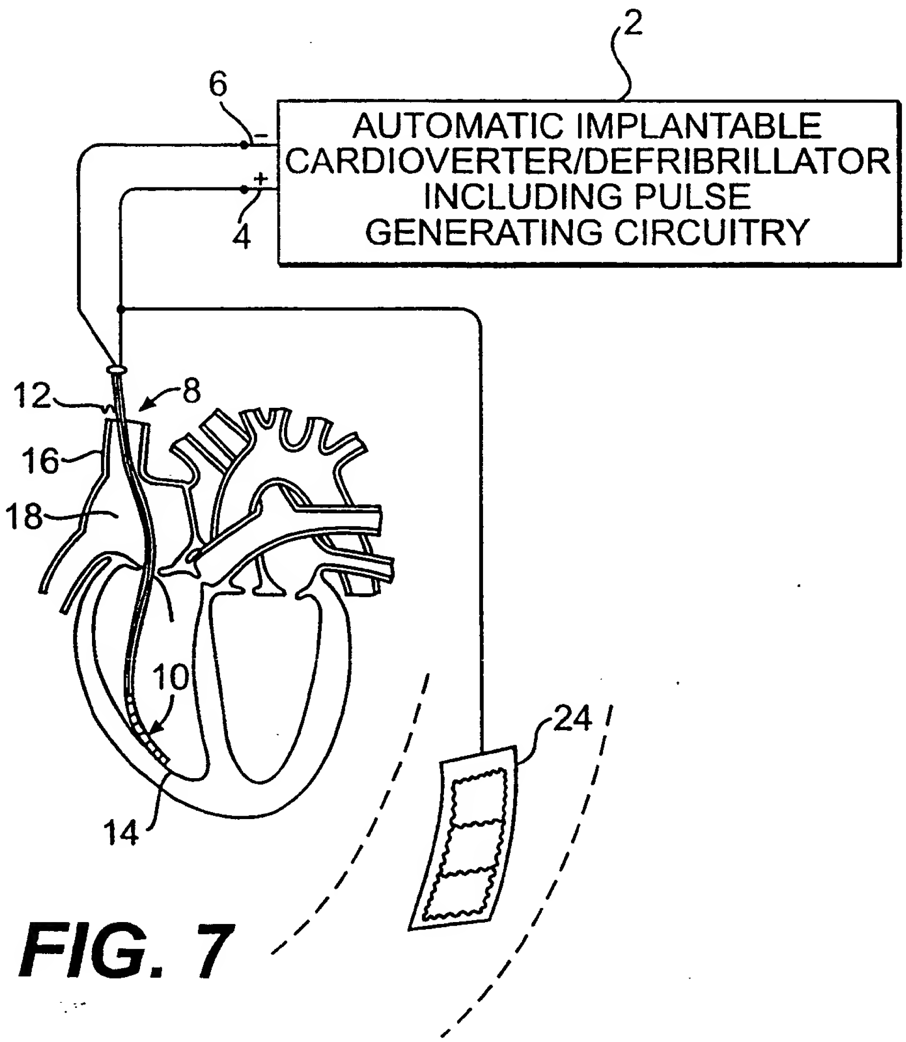
2
6
AUTOMATIC IMPLANTABLE
CARDIOVERTER/DEFRIBRILLATOR
INCLUDING PULSE
GENERATING CIRCUITRY
4
12
8
16
18
10
24
14

FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/00928

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/37 A61N1/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 105 810 A (COLLINS KENNETH A ET AL) 21 April 1992 (1992-04-21) column 6, line 24-26 column 9, line 1 -column 11, line 57; claims 1-11; figures 1-3,7,8	1-7,20, 22,31-34
Y	US 5 718 720 A (PRUTCHI DAVID ET AL) 17 February 1998 (1998-02-17)	1-4, 31-34
A	column 15, line 7-18; figure 10	5-27
Y	EP 0 870 516 A (VITATRON MEDICAL BV) 14 October 1998 (1998-10-14)	5,6,22
A	the whole document	7-21, 23-27, 31-34

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
7 June 2000	15/06/2000

Name and mailing address of the ISA	Authorized officer
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International Application No
PCT/US 00/00928

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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P,A	WO 99 36124 A (MOWER MORTON M) 22 July 1999 (1999-07-22) the whole document	1-27, 31-34
P,A	WO 00 01443 A (MOWER MORTON M) 13 January 2000 (2000-01-13) the whole document	1-27, 31-34
P,A	US 5 871 506 A (MOWER MORTON M) 16 February 1999 (1999-02-16) cited in the application the whole document	1-27, 31-34
P,A	WO 99 61101 A (MOWER MORTON M) 2 December 1999 (1999-12-02) the whole document	1-27, 31-34

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